# Cardiovascular Risk Reduction in Developing Countries

Research to Evaluate Health System Interventions at Primary Health Care Level

> SUMMARY REPORT OF AN IC HEALTH WORKSHOP 9-10 JUNE 2003, LAUSANNE, SWITZERLAND

Integrating Cardiovascular Preventive strategies at Primary Care Level in the 25th year of Alma Ata declaration



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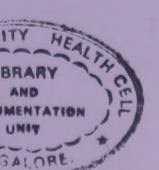
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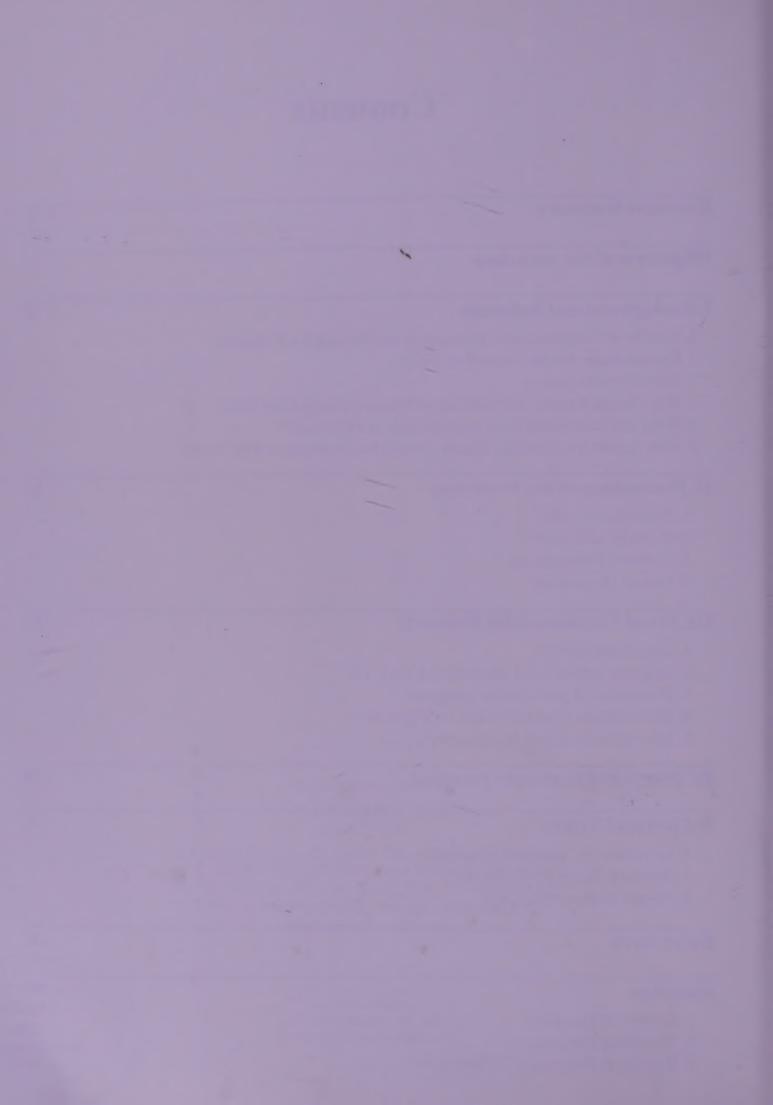
designed & printed by mehra impressions, new delhi email: m\_impres@hotmail.com

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### **Executive Summary**

ardiovascular diseases (CVD) constitute the leading cause of mortality and morbidity in the developed nations. In the developing countries, they are already among the major causes of death and disability. However, owing to the large population size, middle and low income developing countries already have a high absolute burden, currently accounting for three-fourths of the total global mortality and morbidity due to CVD. Moreover, due to changing lifestyles and increased lifespan with a larger proportion of people surviving to middle and older ages, the proportional mortality attributable to CVD as well as the disease burden resulting from CVD are rising sharply in these countries.

Much is already known about the potential of primordial, primary and secondary preventive measures which can reduce the vascular risk substantially. The greatest challenge, at the moment, is not the dearth of knowledge to curb this menace, but how to implement what is already known. Even in the developed nations, there is a wide gap between available knowledge and prevalent preventive practices. Though not well documented, this gap is likely to be wider in developing countries. It is a major challenge to identify the ways to integrate these already known preventive practices into the primary health care system, which forms the backbone of health care delivery in most nations, irrespective of economic and health status. This assumes even greater significance in the primary health care system of the developing nations which are traditionally geared towards the control of infectious and nutritional

While multiple guidelines and recommen-

dations exist for CVD risk reduction in individuals at the primary care level in developed countries, there is less evidence available regarding the effect of implementing these guidelines. Furthermore, such evidence is non-existent in the developing countries in the face of several barriers to implementation of such guidelines and programmes. Also, owing to differences in demographic, socio-economic and cultural milieu, the application of the available evidence derived from the developed nations cannot be assumed to be entirely appropriate for developing countries. The guidelines too would need to be constructed through context- specific and resource-sensitive application of the evidence.

This workshop was organized with the objective of stimulating a discussion on the challenges and feasibility of integrating preventive care for individuals at a high risk of cardiovascular disease, in a cost-effective and evidence-based manner, into the primary healthcare delivery systems of the developing countries. It also aimed to formulate prioritized research questions that are relevant to cardiovascular risk reduction in these settings and to generate a framework for conducting such research for dissemination. The workshop and its recommendations were intended to promote independent investigations whose products will facilitate cardiovascular risk reduction in low and middle income countries.

The participants of workshop represented all the inhabited continents and included countries with different socioeconomic status. Most of the participants were experts in the fields of preventive cardiology and/or health system organization with diverse primary

interests as cardiology, community health, health economics, general practice and primary health care. The meeting was also attended by representatives of World Health Organization, World Heart Federation and International Clinical Epidemiology Network.

The workshop started with relevant background presentations and keynote addresses by the experts in their respective fields. It was followed by country presentations by the participants from developing countries depicting the overall bleak scenario of current cardiovascular research for combating this menace. Issues related to CVD risk reduction at primary health care level were especially under researched, despite their vital importance, emphasizing the need for a concerted and timely effort in this direction by the global community involved in CVD research.

The recommendations emerging from the working group consultations suggested a broad framework for conducting research related to Health System Interventions for Vascular Risk Reduction in Primary Health Care Settings of Developing Countries. This would include: (i) situational analysis, (ii) regional estimates/ algorithms for absolute risk, (iii) evaluation of intervention programmes, (iv) interventions

aimed at health care providers and (v) interventions aimed at consumers. A step wise approach for research, starting with a situational survey, followed by modular intervention studies and finally the initiation of randomized controlled trials, was also proposed.

The workshop concluded with the recommendation that the participants would formulate country specific prioritized research questions, guided by the workshop recommendations, and compete for the seed grants, to be made available by IC Health for project development. Other developing country scientists, interested in this area of research, would also be eligible to compete for these grants.

IC Health has invited project development grant (PDG) proposals to be submitted by 15 November 2003, for the award of seed grants. The Executive Committee of IC Health will select three proposals, based on merit, and disburse US\$ 10,000 for each PDG, in December 2003. Project development is expected to be completed by June 2004. IC Health will subsequently evaluate these developed proposals for further grants, intended to support Pilot/ Phase I studies and would also help the researchers connect with potential donors.

## **Objectives**

- To stimulate a discussion on the challenges and feasibility of integrating preventive care for individuals at a high risk of cardiovascular disease, in a cost-effective and evidence-based manner, into the primary healthcare delivery systems of the developing countries.
- To formulate prioritized research questions that need to be answered by studies for facilitation of above mentioned goal.
- To generate a framework for conducting such research for dissemination, so as to promote independent investigations whose products will facilitate cardiovascular risk reduction in low and middle income countries.



### Part I

## Background and Rationale



# 1. Acknowledging the Burden of CVD in Developing World

#### a. Growing burden of CVD

Cardiovascular disease contributes about 30% (16.5 million) of all global deaths. It also accounted for about 10% of DALYs lost according to WHO 2001 estimate.<sup>1</sup>

In 1998, the low and middle income developing countries accounted for 78% of all deaths and 86.3% of DALYs loss attributable to CVD worldwide.<sup>2</sup> The Global Burden of Disease (GBD) Study has predicted 55% rise in the burden of CVD in the developing countries by year 2020.<sup>3</sup>

Alarmingly, 46.7% of CVD related deaths were reported in less than 70 years of age (most productive years of life) from developing countries in contrast to only 22.8% of death in this age group from developed world.<sup>4</sup> The GBD study has also projected that 6.4 million deaths would occur in the age group of 30-69 years in developing world by 2020.<sup>3</sup>

#### b. Burden of Risk Factors for CVD

In "reducing risks and promoting healthy life", one of the largest research project ever undertaken by WHO and published in the World Health Report 2002, the pattern of risk factors and associated diseases in different economic and demographic regions has been described. (Table-1). Developing countries with low mortality has similar risk factor profile as to the developed nations. With the economic transition from low to high income, the pattern of risks to health changes from poor hygiene and under nutrition related to those related to unhealthy living habits.

## 2. Are there opportunities for the control of CVD?

#### Avoidable burden of risk factors for CVD

Identification of risk factors and its quantification is of great importance in order to calculate the avoidable burden of the disease and framing of cost-effective strategies for prevention.

The estimates suggest that favorable shifts in the population distribution of blood pressure, cholesterol and tobacco use, by only a quarter from their current trends, could avert considerable disease burden<sup>1</sup> (Table 2).

# 3. Barriers to control of CVD in low and middle income countries at PHC level

#### a. Health Policy and Legislation

- Absence of national CVD/NCD prevention programmes in many countries
- Lax or absent tobacco and food related regulations and enforcement.
- Insufficient planning for a health conducive environment (town planning, provision of parks etc)

#### b. Health Care System

- Inadequate chronic disease surveillance systems and registries
- Inadequate framework for research and audits of the health systems
- Inadequate allocation of monetary, administrative and healthcare provider resources for CVD management
- Lack of standardized guidelines for

Table 1: Leading 10 selected risk factors as percentage causes of disease burden measured in DALYs

			_		
High mortality developing countries:		Low mortality developing countries:			
Underweight	14.9%	Alcohol	6.2%		
Unsafe sex	10.2%	Blood Pressure	5.0%		
Unsafe water, sanitation and hygiene 5.5%		Tobacco	4.0%		
Indoor smoke from solid fuels	3.6%	Underweight	3.1%		
Zinc deficiency	3.2%	Overweight	2.7%		
Iron deficiency	3.1%	Cholesterol	2.1%		
Vitamin A deficiency	3.0%	Low fruit & vegetable intake	1.9%		
Blood Pressure	2.5%	Indoor smoke from solid fuels	1.9%		
Tobacco	2%	Iron deficiency	1.8%		
Cholesterol	1.9%	Unsafe water, sanitation & hygiene	1.8%		
Developed countr	ies:				
Tobacco		12.2%	02		
Blood Pressure		10.9%	r 20		
Alcohol		9.2%	por		
Cholesterol		7.6%	ı Re		
Overweight		7.4%	alth		
Low fruit & vegetal	ble intake	3.9%	1 He		
Physical inactivity		3.3%	Vorld Health Report 2002		

Table 2: Attributable and avoidable burdens of important CVD risk factors

1.8%

0.8%

0.7%

Estimated attributable burden			Estimated avoidable burden after 25% distributional transition from 2001				
	In	In 2001		In 2010		In 2020	
	DALY	% Total	DALY	%Total	DALY	%Total	
1. Blood Pressure	64	4.4	25	1.7	27	1.9	
2. Tobacco	59	4.1	17	1.2	22	1.5	
3. Alcohol	58	4.0	15	1.1	16	1.1	
4 Cholesterol	40	2.8	15	1.1	17	1.2	
5 Overweight	33	2.3	13	0.9	15	1.0	

DALYs in Millions; Source: World Health Report 2002

Illicit Drugs

Unsafe sex

Iron deficiency

management of CVD

- Inadequate mechanisms for raising awareness of CVD among care seekers and lack of community involvement in the health framework.
- Lack of standardized referral mechanisms for patients with chronic disease
- Lack of private and public health system coordination
- Under equipped and poorly standardized health facilities for CVD management

#### c. Health Care Providers

- Lack of knowledge and appropriate skill of health care personnel to deal with chronic conditions
- Lack of coordination between private and public health care providers
- Lack of incentive for providing preventive care
- Insufficient emphasis on teaching CVD prevention in undergraduate courses of health care providers

#### d. Community and Patient related

- Socio-economic, religious and cultural barriers to participation of stakeholders in healthcare
- Lack of awareness of factors contributing to cardiovascular risk and of interventions which can effectively reduce that risk
- Lack of social support system

## 4. Why Health System intervention at PHC level?

- PHC is the most important component of health care delivery system accounting for two-third of health care resources in most of developing countries.
- It is the first level of healthcare seeker-

provider interaction.

- Interventions at primary care level provide a unique opportunity for opportunistic screening for risk detection, stratification and management of those at the highest risk for developing CVD. Strategies directed at the primary level have the potential to identify largest number of individuals at risk in a cost-effective manner.
- Few additional human and financial resources are required to introduce novel programs.
- Because of proximity with the community, programs for drug compliance and adherence (essential for chronic conditions) can be suitably implemented.
- Individuals with diseases and at risk are more likely to be receptive to interventions from their primary health care providers.
- Provision of cost-effective and resourcesensitive guidelines, healthcare provider training and strong referral linkages can lead to successful limitation of disability in those with CVD (i.e. high risk primary and secondary prevention).
- A primary care based CVD prevention programme has a higher chance of successful integration with population wide programmes for health promotion and education.
- Primary care programmes provide an opportunity for active participation of community in their healthcare leading to its empowerment.

# 5. What has been learnt from interventions at PHC level?

While many observational studies and randomized trials have demonstrated the efficacy of

interventions for secondary prevention in those with established CVD and of primary prevention in those at high risk for CVD events, there is less evidence for the use of these preventive practices in primary care settings. Some of the primary health care intervention studies found to be useful in the developed countries are - physician directed nurse managed care system<sup>5</sup>, nurse facilitated physician practice<sup>6</sup>, physician and dietician counseling<sup>7</sup>, nurse led primary care interventions<sup>8-11</sup>, combined primary health care and community intervention<sup>12</sup>, physician training and support system<sup>13,14</sup>, physician training in information system and evidence based medicine<sup>15</sup>, training of multi professional teams<sup>16</sup>, sharing responsibilities with the patients<sup>17</sup>, precede-proceed model of health promotion<sup>18</sup>, training in lifestyle based interventions<sup>19</sup>. Providing prevention guidelines to the primary care physicians<sup>20</sup>, computer based clinical support system<sup>21</sup> and preventive care by general practice staff<sup>22</sup> have proven to be ineffective.

'Annexure 1' provides brief description of some of the many studies that have been conducted at primary health care<sup>5-25</sup> and community level<sup>26-33</sup> and also some innovative inter-

ventions in the developing countries<sup>34</sup> to control CVD. These studies have reported variable success of preventive practices on process and hard endpoints, when administered by healthcare workers in varied settings and by different strategies.

# 6. Why research to evaluate Health System Intervention at PHC level?

#### Research is required

- To evaluate various health system intervention techniques in different country settings
- To identify interventions that are cost-effective and country specific
- To identify country specific major lapses in the health systems
- To find out adequacy of health personnel training
- To evaluate various management packages and protocols
- To evaluate sustainability of novel interventions

# Part II Proceedings of The Workshop



#### Workshop Proceedings

The workshop was inaugurated with a welcome address by Professor Stephen McMahon, Chair of the Initiative for Cardiovascular Health Research in the Developing Countries followed by the introduction of the 28 participants.

The participants represented all the continents and countries with different socioeconomic status—High, Middle and Low income countries. Most of the participants were experts in the fields of preventive cardiology and/or health system organization with diverse primary interests as cardiology, community health, health economics, general practice and primary health care. The meeting was also attended by representatives of World Health Organization, World Heart Federation and International Clinical Epidemiology Network.

The objectives, focus, relevance and expected outcomes of the workshop were outlined by Professor KS Reddy, Coordinator of the Initiative and its Scientific Secretariat.

#### 1. Introductory Talks

The session started with the introductory talks relevant to the theme of the workshop as the background information. It started with the acknowledgement of the growing global burden of disease contributed by cardiovascular risk factors and diabetes. This review presented by Dr VP Sharma (IC Health Secretariat) also emphasized the contribution of developing world to the global burden which is over three fourths of the total. Although the burden of risk factors for CVD is slightly less dominant in developing countries with high mortality, the trend in developing countries with low mortality is fast catching up with that of the developed world. But there are ample opportunities to avert considerable disease burden if only 25% shift in the current trend is ensured.

Prof Reddy talked about the concept of comprehensive cardiovascular risk and stated that the risk factors operate in a continuum, and not across an arbitrary threshold. Majority of coronary/stroke events in a population arose from the middle of the risk factor distribution than its high end. Coexistence of risk factors has multiplicative rather than additive effects and absolute risk is dependant on overall risk profile.

Dr Lim, health economist from WHO, described the methods for cost effectiveness analysis. The most cost effective strategies identified in the WHO-CHOICE analysis study included non-personal interventions and absolute risk approach. Some important regional differences as to which non-personal intervention (Salt reduction versus Cholesterol reduction) were more cost-effective were also pointed out. The overall message given was that there is potential for cost-savings by shifting resources from middle activity (risk factor approach) to proximal (absolute risk) or distal (non-personal approach) activity and high risk screening can be tailored to the available resource levels.

Dr Mendis, CVD Coordinator at WHO, described the details of the CVD-Risk Management Package developed by WHO for application in 3 different settings of the developing world. These settings being the health care centre with a non-physician health worker, a centre with a physician and a centre with specialists. She emphasized the need for research to test the package in the field, before wider dissemination.

#### 2. Keynote Addresses

Dr Bengoa, Director for Management of Noncommunicable Diseases at WHO, talked about the innovative reorganization of health care system for integrating vascular risk reduction strategies at primary health care level. He emphasized that the present system which is only suitable for acute care needs to be restructured for the care of chronic conditions by strategies promoting long term adherence.

Prof Mbanya, Executive Committee member of IC Health, profiled the health challenges faced by the developing countries. He elaborated the barriers at the different levels of health system from policy to the patient and community level and emphasized the need for research to overcome them in a cost-effective manner.

#### 3. Country Presentations

Participants from the developing countries presented the scenario of cardiovascular burden and ongoing preventive programmes. The general message was that the CVD burden is increasing rapidly and in some countries it is already the leading cause of morbidity and mortality. However, there is very little evidence of any ongoing intervention programme or research to deal with this problem. Issues related to CVD risk reduction at primary health care level were especially under researched, despite their vital importance. This workshop was

unanimously accepted as very useful and a timely step in this direction. (Country profiles will be published in a separate document).

#### 4. Group Discussions

All the participants were divided into two working groups. Group I discussed the prioritized research questions related to cost-effective interventions for early recognition of risk factors and their reduction, while Group II concentrated its efforts on research questions related to the health system interventions at primary health care level. The outcomes of both the group works were presented, critically discussed and analyzed. Finally a broad framework was derived and discussed. The research questions provided with the background document were also endorsed for use by researchers from different countries with modifications according to the local needs. The stepwise approach for research was also emphasized. Investigators should start with situational analysis followed by modular intervention studies and finally randomized controlled trials of a comprehensive risk detection and risk reduction intervention package.

#### Part III

# Broad Framework for Research at PHC Level



The consultation suggested a broad frame work for conducting research related to Health System Interventions for Vascular Risk Reduction in Primary Health Care Settings of Developing Countries.

#### 1. Situational analysis

- This type of study is the first step to any kind of intervention. It will provide with the information related to the magnitude of the problem, level of awareness about it, prevalent health care practices and capacity at different level of health care system to deal with the problem
- This study should be carried out in different countries, profiling varied socioeconomic settings in each country.
- If adequate data are available from previous studies, then these data can be used instead of repeating similar studies in the scarce resource settings.
- World Health Organization's situational analysis reports for each region, if available, should be examined for relevant information.

#### 2. Regional estimates/algorithms for absolute risk

- Low cost indicators need to be identified and evaluated.
- Algorithms for assessing the absolute risk should be developed and tested at the regional level.
- Existing data from the region can be made use of, in advancing into next level of research.

## 3. Evaluation of intervention programs

Intervention programs, ongoing and/or

planned, need to be evaluated for efficacy, safety, cost effectiveness and process outcomes.

## 4. Interventions aimed at health care providers

- The change in primary health care system from an acute care delivery structure to include the delivery of chronic and preventive care will require multiple interventions to be introduced and evaluated, at the level of health care providers.
- Providing incentives—eg, career opportunities, monetary incentives etc.
- Innovative procedures like Extended DOTS need to be evaluated.
- Improved educational/ training opportunities to the providers
- Partnerships with the Community to be developed and evaluated, especially in the area of non-physician provided health care models and adherence enhancement programmes.

## 5. Interventions aimed at consumers

- An aware and educated community is equally important for the success of any health system change, especially when it requires long term follow up and care as needed in the case of CVD.
- Self referral can be enhanced by health education through different media.
- Adherence/compliance is the most important aspect of chronic disease control which will require many system interventions to be evaluated, especially in the area of patient education programmes.

It was proposed that these researches should be carried out in a step wise approach (Table 3).

#### Table 3. Steps for Research

#### STEP I

#### SITUATIONAL ANALYSIS

(With focus on extent and quality of care related to CVD risk reduction programmes and practices targeting high risk individuals)

- Burden of CVD and Risk factors
- Information on Health Care Infrastructure
- Capacity Assessment
  - providers
  - Administrators
  - Policy and Framework
  - Community

#### STEP II

#### **MODULAR INTERVENTION STUDIES**

(Evaluating specific components for improving detection and management of high risk individuals)

- Risk detection related (eg, opportunistic or targeted screening)
- Risk assessment related practice change (eg, clinical or laboratory based scoring system)
- Risk management related practice change (eg, evaluation of different packages or guidelines)
- Health Care Provider related

  (eg, interventions for promoting the use of guidelines or critical paths)
- Health Care Seeker related (eg, health education, sharing responsibilities)
- Compliance/ Adherence related

  (eg, appointment system, telephonic reminder)
- Health Care system related (eg, physician or nurse led prevention clinics)
- Innovative models evaluation (eg, Iranian or Philippines model)

#### STEP III

#### RANDOMIZED CONTROLLED TRIALS

(eg, cluster randomized community intervention trials for evaluating the cost-effectiveness of composite intervention programmes intended to improve CID risk reduction practices in primary health care)

- Effectiveness of different interventions
- Cost effectiveness of different strategies
- Evaluation of different innovative models

#### Part IV

## Prioritized Research Questions



It is important to find out, through research, how the individual and population based strategies can be introduced in these settings and whether they will be feasible and cost-effective. The workshop agenda focused on generating research questions applicable to Primary Health Care settings and directed towards individuals at high risk of CVD, rather than population based interventions, though the complimentary nature of these are fully recognized even in the context of individual interventions.

Some of the important questions that need to be addressed for operational research, related to interventions for successful integration of chronic preventive care of CVD into primary healthcare infrastructure, are as follows:

- I. Related to cardiovascular disease burden and prevalent practices for preventive care
- 1. Magnitude of the problem- incidence and prevalence of CVD and its risk factors in diverse settings. in low and middle income countries
- 2. Awareness and practices related to CVD risk among the healthcare stakeholders-policymakers, health system managers, providers, care seekers, community and others like NGOs and public/private organizations.
- II. Related to the implementation of CVD preventive practices in primary care
- 1. Research to critically assess delivery of preventive care at primary level in diverse settings –
- 1a. Issues related to infrastructure- physical, health care personnel, drugs and equipment, settings, referral systems
- 1b. Issues pertaining to mechanisms for

- community participation and self referral of those at high risk for CVD
- 1c. Mechanisms for effective compliance and adherence to lifestyle related as well as pharmacologic advice.
- **1d.** Cost-effective analyses for the various options available.
- 2. Efficacy and feasibility of integrating current preventive practices related to CVD into primary health care settings.
- 3. Assessment of capacity at several levels to meet the future needs pertaining to CVD control and areas requiring reinforcement.

## III. Related to the CVD prevention directed at PHC settings

- 1. Evaluation of strategies for detection of vascular disease and vascular risk factors at primary health care level
- 1a. Related to risk detection
- i. Opportunistic Screening:
- Screening all adults presenting to primary center for CVD risk factors
- Screening the patients, who are in high-risk age groups and present to the healthcare provider for any ailment, for CVD risk factors
- Measuring blood pressure of all adult patients and accompanying adult individuals
- ii. Community Screening:
- Meareening people in eligible age group at their work places for CVD risk factors
- Screening at health camps
- 1b. Related to risk assessment & management
- i. Criteria for identification of those at medium risk and at high risk for developing a CVD event
- ii. Criteria for investigation and referral, for further risk stratification in appropriate cases.. iii. Essential and optimal packages



- for vascular risk reduction in those at elevated risk.
- iv. Development, testing and dissemination of appropriate, simplified and cost-effective guidelines for CVD management.
- 2. Issues related to healthcare provider training
- 2a. Critical appraisal/testing of different methods for enhancing awareness and adoption of prescribed guidelines for CVD risk detection and management.
- **2b.**Selection of healthcare providers depending on resources, settings and health infrastructure for delivery of preventive care.
- 3. Issues related to follow-up and long-term adherence
- **3a.** To evaluate strategies for sustained follow-up of at risk individuals
- Appointment for next visit
- Telephonic reminder
- Postal reminder and health education pamphlets
- Notice board of organizations
- **3b.** To evaluate barriers to the adherence of treatment
- i. Health Care System related-
  - Medication distribution system
  - ♦ Insurance reimbursements
  - Duration of consultation
  - Provider knowledge about ensuring adherence
  - Follow up practices
  - Ability to establish community support
  - ♦ Incentives and feedback on performance
  - ◆ Time spent on communication of side effects and importance of adherence
  - Availability of Behavior Therapist / Psychologist
- ii. Patient related—
  - Sharing of responsibilities with the

#### patients

- ♦ Level of Health Education
- Fear of dependence
- Fear of stigmatization
- Motivation level
- Psychosocial stress level
- Exchange of experiences among
- patients Sharing experience with care provider

#### 4. Others

- **4a.** To evaluate different modalities of health education of individuals relevant to the local context
- **4b.** Availability of cheap, evidence-based and proven medications for CVD management and secondary prevention
- **5.** Evaluation of models of primary care based CVD prevention which have been studied in the developed nations.
- 5a. Physician directed interventions.
- 5b. Nurse facilitated physician practice
- **5c.** Physician directed and nurse managed care system
- 5d. Physician directed dietician counseling
- 5e. Nurse led preventive clinics
- **5f.** Combined Primary health care and community interventions
- 5g. Training of entire professional teams
- 5h. Computer based support system
- 5i. Precede-Proceed model for health promotion
- 5j. Training in healthy lifestyle based intervention

The focus has to be on research (knowledge translation research + new knowledge generation research) as relevant to and applicable in the settings of low and middle income countries.

# Part V Course of Action



#### 1. Invitation for research proposals

As per the workshop recommendations, IC Health has invited proposals for project development grant (PDG) till 15 November 2003, for the award of seed grants. Apart from the workshop participants, other developing country scientists, interested in this area of research, would also be eligible to compete for these grants. This invitation for proposal was posted to all participants as well as on various research web sites including IC Health, World Heart Federation and INCLEN web sites.

#### 2. Project Development

Executive Committee of IC Health will select three proposals, based on merit, and disburse US\$ 10,000 for each PDG, in December 2003. Project development is expected to be completed by June 2004.

#### 3. Project Implementation

IC Health will subsequently evaluate these developed project proposals for further grants, intended to support Pilot/ Phase I studies, and would also help the researchers connect with potential donors.

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### Annexure 1: Review of Literature

#### Primary Health Care Intervention Studies

## 1. Physician Directed and Nurse managed Care System

The Stanford case management system for coronary risk factor modification after Acute MI evaluated the efficiency of physician directed and nurse managed care system. Significantly lower 1 year plasma LDL level (107 vs 132 mg / dl) and higher smoking cessation rates (70 % vs 53 %) were seen in special care group<sup>5</sup>.

#### 2. Nurse facilitated Physician practice

Forty six health service organizations from 100 sites in Ontario were recruited to evaluate a multifaceted intervention, delivered by nurses trained in prevention facilitation to improve prevention in primary care. At 18 months follow up, there was an absolute improvement of 11.5% (P<0.001) for the index of preventive performance and improvement of 7.2% (P<0.008) in the recommended maneuvers. It was concluded that the tailored multifaceted intervention delivered by nurse facilitators was effective in modifying physicians practice patters and significantly improved preventive care performance.<sup>6</sup>

## 3. Counseling by Physician and Dietician

Tromso family trial recruited 1373 pts of CHD or at high risk of CHD and their wives (809), who were counseled by primary care physician and dietician for diet, smoking cessation

and exercise. At 6 years, small reduction in cholesterol was noted but no effect on smoking or BP.<sup>7</sup>

#### 4. Nurse led Primary Care interventions

- a. The Oxcheck study was conducted to determine the effectiveness of health checks performed by nurses in Primary care, in reducing the risk factors for CVD. 2205 men and women in 35 64 age group were allocated to intervention and 1916 in control group and were followed up for 3 years. Statistically significant changes in mean total cholesterol, SBP, DBP and BMI were observed which decreased by 3.1% (Men = 1.6 %, Women = 4.5 %), 1.9 %, 1.9 % and 1.4 % respectively in intervention group. No significant change in prevalence of smoking was detected.<sup>8</sup>
- b. British family heart study recruited 9384 men & women aged 40-59 in a randomized controlled trial to evaluate cardiovascular screening & nurses led intervention in general practice. At 1 year, an overall reduction in cardiovascular risk of 12% was achieved.<sup>9</sup>
- c. A nurse based pilot program included comprehensive CVD risk assessment, patient education, counseling & algorithm guided individualized care plans to reduce cardiovascular risk factors in a primary care setting. A total of 436 patients at a primary care clinic in Minneapolis were enrolled in 2 years. Statistically significant reductions were achieved in SBP (from 155.8 to143.4 mm of Hg), DBP (from 94.4 to 84 mm of Hg), dyslipidemia (LDL from 4.15 to 3.80 mmol/l) and smoking cessation (30% 12 out of 40).<sup>10</sup>

d. The effects of nurse led clinics in primary care on secondary prevention was evaluated on 1343 CHD patients under 80 yrs of age for 4 yrs. Significant improvements were shown in all components of secondary prevention except smoking. At 4.7 years cumulative death rates were 14.5% vs 18.9% (p= 0.03) and event rates were 14.2% vs18.2% (p=0.05) in intervention and control groups respectively.<sup>11</sup>

## 5. Primary Health Care +Community intervention

The Norsjo community intervention program was unique due to its combined approach. In this, systematic risk factor screening and counseling by primary care physicians were carried out at the same time as the community intervention were raising the public awareness. It was possible to create local health promotion collaboration between health care providers, schools, municipal authorities, grocery stores, and the public. After 10 years of intervention significant changes in total cholesterol and systolic BP has been noted. The predicted coronary heart disease mortality reduced by 36% in the intervention area.<sup>12</sup>

#### 6. Physician training & Support System

The Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH) randomized 45 primary care physicians into usual care (UC), physician training (PT) and training plus a structured practice environment (TS). After 1 yr of follow up group (TS) patients had 8% decrease in intake of fat, 12% decrease of saturated fat, average weight loss of 6.3 and 6.9 mg dl decrease in LDL compared to group (UC) and (PT) patients. Average counseling time was 9.2 min. This demonstrates that counseling accompanied by office support system is a low-cost and effective intervention. (Support system- algorithms, prompts,, simple dietary assessment tools). 13,14

## 7. Physician training in information system and evidence based medicine

The PIER trial was aimed to investigate the effectiveness of educational interventions developed in primary care on recording prescribing and control of risk factors by general practitioners of inner London. The participating practices were randomly allocated to information, evidence, both or neither groups. After 18 months, adequate recording of risk factors showed the greatest improvement in the information plus evidence group (19.9% increase). Prescription of lipid lowering drugs (4.4% increase) & mean cholesterol (0.7% mmol/1 decrease) improved in the combined group This combined training in information systems and evidence based medicine of primary care practiceners were very effective and recommended for further intervention.15

#### 8. Training of multi professional teams

Quality improvement program for cardiovascular disease risk factor recording was undertaken in two primary health care centers of Helsinki. The intervention program consisted of lectures and meetings of multi professional teams, development of local guidelines and structured risk factor recording sheet. Risk factors were better recorded, more high risk CVD patients were detected and differences in the trends for body weight, BMI, total cholesterol and glucose levels were observed. 16

## 9. Sharing responsibilities with the patients

165 pts with type 2 DM, HTN and hyperlipidemia were randomly allocated to standard care (SC) or to a patient participation program (PP) in primary care setup. At 4 years, mean BP was 148 / 88 vs 142 / 84 mm of Hg (P = 0.02), mean LDLC was 124 vs 114 mg / dl

(P = 0.01), and mean HbA1C was 8.9 vs 8.2% (P = 0.04) in the SC and PP groups respectively. There were 36 CV events in SC group vs 23 in PP group (P = 0.04). Sharing the therapeutic responsibility with the patient of DM by teaching them to monitor their risk factors has significant beneficial implications.<sup>17</sup>

## 10. Precede-Proceed Model of Health Promotion

Study to test the short term and long term effectiveness of a four week residential program (lectures, group discussions and practical sessions) for 2500 primary care patients to control obesity and other risk factors for CVD was undertaken in Sweden. Dramatic reductions in weight and BP occurred during residential during residential program and continued up to 1yr. After 5 yrs, the total mean weights of obese patients were still 5 kg lower and DBP & SBP of hypertensives were 15 & 20 m Hg lower. The study illustrates an effective application of the Precede-Proceed model of health promotion planning.<sup>18</sup>

#### 11. Training based lifestyle intervention

Long term beneficial effects of a primary health care intervention program for women revealed that CVD risk factors in those who participated in a 3-months course in healthy lifestyle showed reduction in BP and no weight gain over 8 yrs.<sup>19</sup>

## 12. Guidelines to Physicians for prevention of CVD

This was evaluated by the EUROASPIRE I & II studies which was undertaken in 21 centers of 9 countries across Europe. This study revealed ineffectiveness of CHD prevention guidelines on practicing physicians for modifying the adverse lifestyle trends though some impact was seen on the prescription of preventive drugs. This needs to be validated in

middle and low income countries.<sup>20</sup>

## 13.Computer based Clinical support system

The effect of a computer based clinical decision support system and a risk chart on absolute cardiovascular risk, BP and prescription was evaluated on 614 hypertensive pts in a randomized controlled trial. The computer based clinical decision support system did not confer any benefit in absolute risk reduction whereas uses of chart guidelines were associated with significant reduction in systolic BP.<sup>21</sup>

## 14. Preventive care by general practice staff

The CELL study enrolled 681 subjects, aged 30-59 years with at least two cardiovascular risk factors in addition to moderately high lipid concentrations, were randomly allotted to intensive health care advice through six group session and usual care groups. The study was conducted in 32 rural health centers of Sweden where one doctor and one or two nurses from each centre participated. After 18 months of follow up little additional benefit was seen in the intensive health care advice group compared to the usual care. (Cholesterol decreased by 1.15 mmol/l and overall Framingham risk score dropped by 0.068). They concluded that it is difficult to make an important impact on cardiovascular risk in primary care by using only the practice staff.22

#### 15. Intensive intervention strategy

In the Oslo study, 1232 males, 40-49 years of age with hypercholesterolemia and mild hypertension were given step 1 diet and enrolled in smoking cessation program in the intervention group. At 5 years, significant reductions were observed in LDL, TGL, smoking, coronary mortality and total mortality (13%, 20%, 45%, 55% and 33% respectively).<sup>23</sup>

#### 16. High risk strategy

a. In Finnish businessmen study, 1222 high risk men volunteers aged 40-55 were counseled for diet, smoking, exercise, antihypertensive drugs and cholesterol lowering drugs. At 5 years follow up, large reduction in BP, cholesterol & smoking rates were noted. However, the CHD event rates were slightly higher probably due to adverse effects of drug treatment.<sup>24</sup>

b. MRFIT was a randomized, controlled clinical trial to test the effect of comprehensive multifactorial intervention program on mortality from CHD in 12,866 high-risk men (35-57 yrs) over 7 years. The risk factors intervened were HTN, increased cholesterol and smoking. After 7 yrs of follow up, no significant difference in mortality was seen (41.2 SI vs 40.4/1000 UC). Mortality from CHD was 17.9/1000 in SI and 19.3/1000 in UC group. The reason probably was that SI group did not change risk factors as much but UC group did so more than expected. The most important impact was noted in smoking cessation especially as a result of a 10 wk group support session.25

# Community Intervention Studies

Most coronary events occur in majority of people with moderately increased risk rather than the few with very high risk. Thus, prevention efforts in the community are concentrated on larger population with moderate risk.

1. The WHO European Collaborative Multi Factorial Trial was conducted in UK, Belgium, Italy, Poland and Spain. Subjects in the age group of 40-59 years from two factories in each country were recruited in the study. The study showed 11.1% decrease in combined risk

estimate, 19.4% decrease in high risk estimate, 7.4% decrease in CHD, 3.9% decrease in fatal + non fatal MI and 3.9% decrease in death. The more individualized attention, the better the outcome.<sup>26, 27</sup>

2. The Minnesota Heart Health Program was Primary prevention program for 500,000 people from six communities with an intention to decrease population risk rather than individual risk. Interventions included HTN prevention & control, dietary education & counseling for lowering cholesterol, smoking cessation & encouragement of physical activities. Subjects were assessed for 7 years for RF & 13 years for mortality. The changes in IC were in favorable direction, however none were statistically significant.<sup>28</sup>

3. Stanford Five City Project —Treatment cities (N= 122,800) received 5yr low cost comprehensive program using social learning theory, communication behavior change model, community organization principles & social marketing methods that resulted in about 26 hrs of exposure to multifactor education. Surveys carried out 3-5 years after demonstrated significant reduction in cholesterol level (2%), BP (4%), resting pulse rate (3%), smoking rate (13%), composite total morality risk score (15%) & CHD risk score (16%) among the intervention groups.<sup>29</sup>

4. Pawtucket Heart Heath Program- In this study, 140,000 subjects were in each of control and intervention group. The study was designed to produce 6% in mean cholesterol, 6 mm of Hg in mean SBP, 30% in smokers and 15% in CV event rates.<sup>30</sup>

5. The North Karelia Project was one of the first population based cardiovascular disease prevention program. The intervention achieved significant reduction in smoking, serum



cholesterol levels and blood pressure levels in the community leading to large reductions in CVD mortality (50.1% in males and 63.5% in females), CHD mortality (53.4% and 59.8%) and all cause mortality (39.5% and 40.4%)<sup>31</sup>. Moreover, the association between social support and mortality from CHD was quite strong. Socially isolated people had 200-300% increased risk of death over 5-9 yrs.<sup>31, 32</sup>

6. The Working Healthy Project was a worksite health promotion trial involving 26 manufacturing unit and 2055 participants. At the end of trial, participants in intervention group significantly increased their exercise behavior, consumption of fruits, vegetables and fibers. But there was no significant change in the intake of calories from fat or smoking cessation. This study suggests the feasibility of multiple risk factor interventions at worksites with beneficial effects.<sup>33</sup>

# Novel PHC Interventions in Developing Countries

Most of the studies for CVD prevention in developing countries have been related to prevalence of CVD and its associated risk factors. There are very few studies on intervention and almost entirely at community

level. There is hardly any study of intervention at primary care level. But some countries have introduced innovative systems at PHC level for control of chronic diseases.

- 1. Iran has implemented innovative community based care system with remarkable success. Although most of the activities were centered to control of tuberculosis, malaria and mental disorders, recently hypertension and diabetes has also been included in the same areas. The important factors for the success of PHC have been attributed to the establishment of combined Ministry of Health and Medical Education with proper referral system and active involvement of the community in the planning and implementation of health services.<sup>34</sup>
- 2. Philippines is going ahead with its ambitions National Health Sector reforms to deal with chronic conditions by focusing activities upon: Guidelines and clinical pathways, Surveillance systems, Registry systems, Community based approaches and Research health financing.<sup>34</sup>
- 3. Ghana's Ministry of Health along with academic institution and private industry have initiated national diabetes control program with significant success.<sup>34</sup>

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## Annexure 3: Programme Schedule

Monday, 9th June 2003 (Day 1)			
0900 – 0905 hrs	Welcome address	Dr S. MacMahon	
0905 – 0915 hrs	Objectives of the workshop	Dr KS Reddy	
0915 — 1045 hrs	SESSION: I	Chair: Dr S MacMahon	
	Introductory talks:		
	1. Global burden of disease contr factors and diabetes.	ibuted by cardiovascular risk Dr VP Sharma	
	2. The concept of comprehensive framework for defining and reduc disease.	he concept of comprehensive cardiovascular risk-a ework for defining and reducing high risk of vascular se.  Dr KS Reddy	
	3. WHO risk reduction package fo	or low resource settings.  Dr S Mendis	
	4. Cost-effective strategies for card	diovascular risk reduction. Dr S Lim	
1045 – 1100 hrs	Tea Break		
1100 – 1130 hrs	General discussion on cost-effective interventions for CV risk reduction		

1130 – 1230 hrs	SESSION: II	Chair: Dr K S Reddy
	Keynote Talks:  1. Reorganization of health systems for integrating vascular risk reduction strategies, strengthening delivery of chronic care and promoting adherence.  Dr Rafael Bengoa  2. Challenges of primary health care in low and middle income countries facing double/triple burden of disease in scarce re-	
1230 –1300 hrs	source settings.	Dr Jean Claude Mbanya
1250 –1500 ms	General discussion on reorganization of primary health care	
1300 –1400 hrs	Lunch break	
<u>1400 – 1500 hrs</u>	SESSION: III	Chair: Dr S Mendis
	Country Presentations:  Each Country will get 10 min (5 min for Presentation + 5 min Cameroon China Guatemala India Lebanon	n for Discussion) Dr JC Mbanya Dr JL Tang Dr CM Montano Dr V Chaturvedi Dr M Khogali
1500 – 1515 hrs	Tea Break	
1515 – 1615 hrs	SESSION: IV	Chair: Dr F Paccaud
	Country Presentations (Cont.)  Mexico South Africa Tanzania & Seychelles Thailand Venezuela	): Dr JA Ramirez Dr K Steyn Dr P Bovet Dr W Aekplakorn Dr R Granero
1615 – 1630 hrs	Tea Break	

1630 - 1800 hrs

**SESSION: V** 

Working Group I

Chair: Dr K Steyn

Rapporteur: Dr Vivek Chaturvedi

I. Development of cost-effective interventions for early recognition of vascular risk and risk reduction: identifying prioritized research questions

The working group (I) will address the following issues:

- What evidence is required to develop algorithms for the detection of high risk individuals?
- What evidence is required to implement intervention programs for cardiovascular disease prevention?

#### Working Group II

Chair: Dr M Khogali Rapporteur: Dr P Bovet

- I. Development of health systems interventions for integrating vascular risk reduction packages into primary health care settings, implementation strategies and their evaluation: identifying prioritized research questions
- The working group (II) will address the following issue:
- What evidence is required to guide efforts to restructure primary health care to deliver long-term preventive care?

#### Tuesday, June 10, 2003 (Day 2)

0900 - 1030 hrs

**SESSION: VI** 

Chair: Dr S Leeder

Presentation of working group reports and discussion

1030 - 1045 hrs

Tea Break

1		
1045 – 1230 hrs	SESSION: VII	
	Co-chairs: Dr Rodolfo Dennis & MacMahon Rapporteurs: Dr JA Ramirez & Dr Pascal Bovet	
	<ul> <li>Whole group works together to design a research framework to guide future studies intended to develop and evaluate health system interventions for vascular risk reduction in primary health care settings: Choice of study design, choice of intervention package, outcomes, evaluation process, logistics of integration with existing health care systems, public-private partnerships, capacity development.</li> </ul>	
	• Discussion will be initiated by brief presentations of projects under development in Thailand (Dr W Aekplakorn) and India (Dr R Joshi).	
1230 – 1330 hrs	Lunch Break	
1330 – 1530 hrs	SESSION: VIII	
	Group work continues (as above)	
1530 — 1545	Tea Break	
1545 – 1700 hrs	SESSION: IX Chair: Dr KS Reddy	
	Future plans (pilot studies; steering committee; protocol development for grant applications; networking among investigators and experts)	



# INITIATIVE FOR CARDIOVASCULAR HEALTH RESEARCH IN THE DEVELOPING COUNTRIES (IC Health)

An international partnership programme initiated by Global Forum for Health Research and World Health Organization

IC Health was born in 1999 as a joint programme of the Global Forum for Health Research (GFHR) and the WHO (NCD Cluster). The partnership has since expanded to include: Institute of Medicine (USA), World Heart Federation, National Public Health Institute (Finland), World Hypertension League, International Obesity Task Force, International Institute for Health and Development (Australia), Institut Universitaire de Médecine Sociale et Préventive (Switzerland), Health Canada, Centres for Disease Control (USA), National Institutes of Health (USA), the International Clinical Epidemiology Network (INCLEN), Medical Research Council (South Africa) and National Public Health Institute (Mexico). The partnership thus represents a range of international research agencies, public health institutes and health NGOs. The World Bank is also providing funds via GFHR. The expanded network would include agencies and institutions, in the developing countries, who are involved in activities related to CVD prevention and control.

IC Health is governed by a *Partnership Council*, which is currently chaired by Prof. Stephen MacMahon, Director, Institute for International Health, Sydney, Australia. An *International Scientific Advisory Committee*, comprising of eminent scientists from developing and developed countries, guides and monitors the research projects. These research projects are coordinated by a *Scientific Secretariat* headed by Prof K. Srinath Reddy, All India Institute of Medical Sciences, New Delhi. Each of the projects has a developing country scientist as a coordinator and is guided by a *Project Advisory Committee* of international scientists with project related expertise.

### ROLE OF IC HEALTH RESEARCH PATHWAY Global Networks of Partnerships for research Scientists and donors Priority Setting through Purpose of research **Expert consultations** Capacity Building for Process of research Planning and conducting research **Critical Appraisal for Products** of research Context-specific & Cost-effectiveness **Advice and Advocacy Policy and Practice** for evidence-based. Change interventions Planning and Evaluation **Programmes** for of programme components CVD control









## INITIATIVE FOR CARDIOVASCULAR HEALTH RESEARCH IN THE DEVELOPING COUNTRIES

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